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16 Attorneys for Plaintiff
MINERVA SURGICAL, INC.

17
18 **IN THE UNITED STATES DISTRICT COURT**
19 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

20
21 Minerva Surgical, Inc., a Delaware corporation,) CASE NO.: 5:17-cv-02013
22)
23 Plaintiff,) DEMAND FOR JURY TRIAL
24)
25 v.)
26) **COMPLAINT FOR PATENT**
27 Hologic, Inc., a Delaware corporation; AND) **INFRINGEMENT**
28 CYTYC Surgical Products, LLC, a)
Massachusetts limited liability company,)
Defendants.)
)

COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to Section 1338 of the Title 28 of the United States Code, Plaintiff Minerva Surgical, Inc. (“Plaintiff” or “Minerva”) alleges for its Complaint against Defendants Hologic, Inc. (“Hologic”) and CYTYC Surgical Products, LLC (“CYTYC”) (collectively “Defendants”), on personal knowledge as to Minerva’s own actions and on information and belief as to the actions of others, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, including 35 U.S.C. §271 et. seq.

THE PARTIES

2. Plaintiff Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA 94063.

3. On information and belief, Defendant Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts 01752.

4. On information and belief, Defendant CYTYC is a limited liability company organized and existing under the laws of the State of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts 01752.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. The Court has personal jurisdiction over Defendants. On information and belief, Defendants have had continuous and systematic contacts with this District, regularly transact business within this District, and regularly avail themselves of the benefits of this District. On information and belief, Defendants, directly or through intermediaries (including sales agents and others), use, offer for sale, sell, import, and/or distribute to others for such purposes,

1 endometrial ablation products for the treatment of abnormal uterine bleeding in the United States
2 and in this District.

3 7. For example, Defendants sell the NovaSure[®] ADVANCED Impedance Controlled
4 Endometrial Ablation System (“NovaSure ADVANCED”) in the United States and in this
5 District.

6 8. As another example, Defendants have availed themselves of this District by filing
7 suit against third parties in this District. *See, e.g., Hologic, Inc. et al. v. SenoRx, Inc.*, Case No.
8 5-08-cv-00133 (N.D. Cal.).

9 9. Venue is proper in this District under 28 U.S.C. §§ 1391(b)-(c) and under
10 §1400(b) as, among other reasons, Defendants are subject to personal jurisdiction in this District
11 and a substantial part of the events giving rise to the claims for relief occurred in this District.

12 **INTRADISTRICT ASSIGNMENT**

13 10. Pursuant to Local Rule 3-2(c), Intellectual Property Actions are assigned on a
14 district-wide basis.

15 **BACKGROUND**

16 11. The endometrium (tissue lining of the uterine cavity) can sometimes be the source
17 of abnormal uterine bleeding in women. This condition is sometimes referred to as menorrhagia,
18 or heavy menstrual bleeding. Over 10 million women in the United States alone suffer each year
19 from menorrhagia, which can lead to iron deficiency, severe anemia, shortness of breath, and
20 increased risk of heart problems.

21 12. Minerva’s entire business is focused on developing, manufacturing, and supplying
22 a medical endometrial ablation device for treating this condition. The product is called the
23 Minerva[®] Endometrial Ablation System (“Minerva EAS”).

24 13. Minerva’s device works by thermally ablating the endometrium. Once inserted
25 into the uterine cavity, Minerva’s patented technology mechanically deploys Minerva’s Plasma
26 Formation Array (the distal end of Minerva’s device) into its open state so that the short—and
27 often in-office—ablation procedure can begin. Minerva’s patented device uses a high voltage
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1 radio frequency (RF) electric current to ionize a neutral gas that is fully contained and circulated
2 within a smooth, sealed silicone membrane, turning the gas into plasma. The plasma heats the
3 interior surface of the silicon membrane, and the resulting heat is conducted to the tissue in
4 contact with the membrane. The exterior of the membrane thus heats the tissue directly, and
5 further relies on retained moisture in the uterine cavity as an additional mechanism to assist in
6 ablating interstices and other natural folds in the uterine tissue that otherwise may not be in
7 contact with the membrane, thereby providing a more even ablation using significantly less
8 power than other competitive devices.

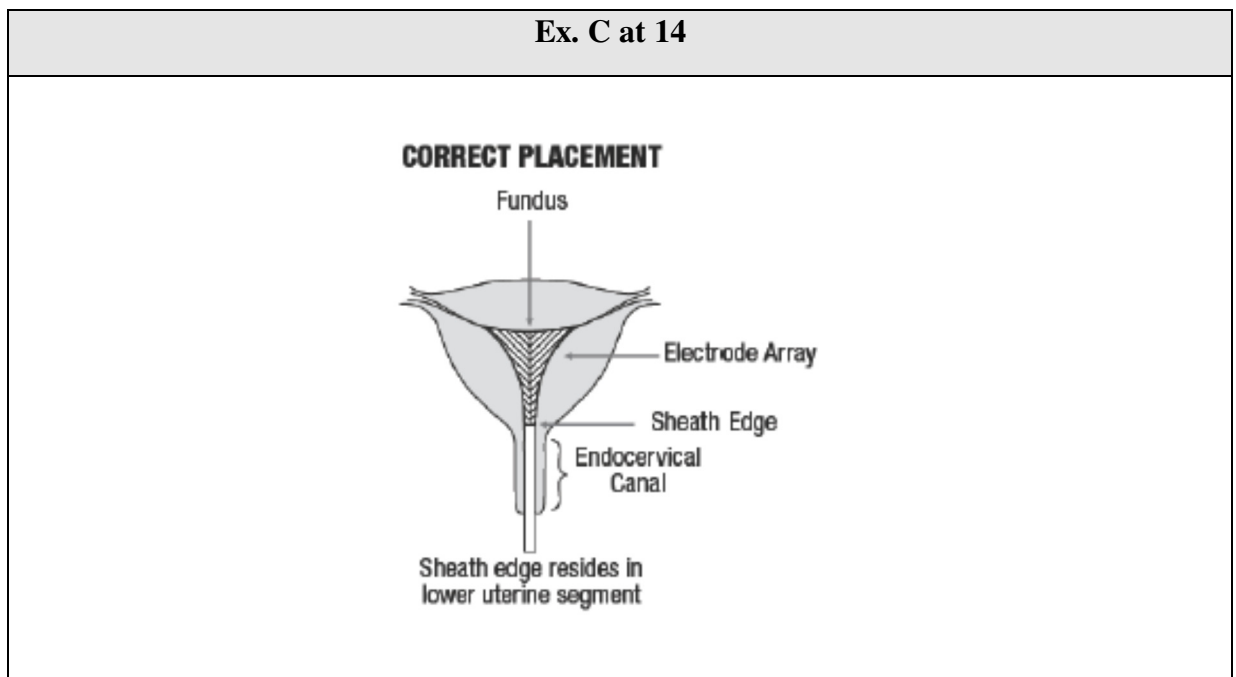
9 14. Minerva has invested years and significant resources into researching, developing,
10 testing, obtaining FDA approval for, and bringing to market the Minerva EAS that is designed to
11 improve the efficacy of endometrial ablation procedures. In fact, the FDA-approved post-
12 treatment success rate (heavy menstrual bleeding reduced to a normal level or less) for the
13 Minerva EAS is 91.8%, and the post-treatment amenorrhea rate (menstrual bleeding totally
14 eliminated) is 66%. (*See* Exhibit A (Minerva Summary of Safety and Effectiveness Data
15 (SSED)), at 21, *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf14/p140013b.pdf.)
16 The FDA-approved post-treatment success rate for the NovaSure ADVANCED is 77.7%, and
17 the post-treatment amenorrhea rate (menstrual bleeding totally eliminated) is 36%. (*See* Exhibit
18 D (Novasure Summary of Safety and Effectiveness Data (SSED)), at 18, *available at*
19 https://www.accessdata.fda.gov/cdrh_docs/pdf/P010013b.pdf.)

20 15. In order to protect its investments and cutting-edge intellectual property, Minerva
21 regularly files patents with the United States Patent and Trademark Office (“USPTO”), and has
22 been granted twenty-five issued patents and has numerous pending applications. One of these
23 patents is U.S. Patent No. 9,186,208 (“the ’208 patent”). A true and correct copy of the ’208
24 patent is attached as Exhibit B.

25 16. On information and belief, Defendants have been competing and continue to
26 directly compete with Minerva using Minerva’s own patented technology since at least February
27 2017 by making, using, offering for sale, selling, and/or importing into the United States for
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subsequent sale or use the NovaSure ADVANCED. Defendant Hologic's website announced the very recent launch in the United States of its NovaSure ADVANCED on February 2, 2017. A true and correct copy of the NovaSure ADVANCED Instructions for Use and Controller Operator's Manual, which can be obtained from Defendants' website (http://novasure.com/sites/novasure/files/MAN-03523-001_009_01_new.pdf), is attached as Exhibit C.

17. The NovaSure ADVANCED is a system for endometrial ablation, as advertised in the NovaSure ADVANCED Instructions for Use and Controller Operator's Manual. *See, e.g.*, Ex. C at 2. The NovaSure ADVANCED comprises an elongated shaft with a working end having a compliant energy-delivery surface, as shown in the figure below. The energy-delivery surface is expandable to a selected planar triangular shape configured for deployment to engage the walls of a patient's uterine cavity:



18. The energy-delivery surface of the NovaSure ADVANCED is actuatable by an interior expandable-contractable frame:

Ex. C at 13

19. The NovaSure website demonstrates that the frame of the NovaSure Advanced has flexible outer elements in lateral contact with the compliant surface and flexible inner elements not in lateral contact with the compliant surface. On information and belief, the inner and outer elements have substantially dissimilar material properties.

NovaSure website, <http://www.novasure.com/hcp/novasure-advanced>**CLAIMS FOR RELIEF****(Defendants' Direct and Indirect Infringement of the '208 Patent)**

20. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

21. On November 17, 2015, the USPTO duly and legally issued the '208 patent, entitled "Systems for Endometrial Ablation," to Csaba Truckai and Akos Toth as inventors.

1 22. A true and correct copy of the '208 Patent is attached as Exhibit B.

2 23. Plaintiff is the assignee and lawful owner of all right, title, and interest in and to
3 the '208 patent.

4 24. Defendants had knowledge of the '208 patent since at least February 8, 2016. In
5 addition, Defendants knew or should have known that the sale, offer for sale, use, manufacture,
6 and/or importation of the NovaSure ADVANCED would infringe at least claim 13 of the '208
7 patent due to its use of Minerva's patented technology.

8 25. On information and belief, Defendants have directly infringed and continue to
9 directly infringe, literally and/or through the doctrine of equivalents, at least claim 13 of the '208
10 patent by making, using, offering for sale, selling, and/or importing into the United States the
11 NovaSure ADVANCED in violation of 35 U.S.C. § 271(a). Further, on information and belief,
12 Defendants' customers directly infringe at least claim 13 of the '208 patent by using the
13 NovaSure ADVANCED in violation of 35 U.S.C. § 271(a).

14 26. On information and belief, Defendants have indirectly infringed and continue to
15 indirectly infringe the '208 patent, including by inducing third parties, such as Defendants'
16 customers, to use the NovaSure ADVANCED in violation of 35 U.S.C. § 271(b). On
17 information and belief, Defendants have knowingly induced infringement and have had specific
18 intent to induce infringement of the '208 patent by their activities relating to the marketing, sales,
19 support, and distribution of the NovaSure ADVANCED, including, for example, providing
20 through Defendants' website advertisements and marketing materials instructing and
21 encouraging the use of the NovaSure ADVANCED.

22 27. On information and belief, Defendants' infringement has been and continues to be
23 willful, wanton, deliberate and/or willfully blind, thereby making this an exceptional case under
24 35 U.S.C. § 285 and entitling Plaintiff to enhanced damages under 35 U.S.C. § 284.

25 28. As a result of Defendants' infringement of the '208 patent, Plaintiff has suffered
26 and continues to suffer damages and other harms, including irreparable harm for which there is
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1 no adequate remedy at law unless this Court enjoins the making, using, offering for sale, selling,
2 and/or importing into the United States the NovaSure ADVANCED.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiff requests entry of judgment in its favor and against Defendants
5 as follows:

6 A. Judgment in favor of Plaintiff, and against Defendants, that Defendants have and
7 continue to directly and indirectly infringe one or more claims of the '208 patent, as alleged
8 herein;

9 B. A preliminary and permanent injunction against Defendants and their parents,
10 subsidiaries, affiliates, successors, predecessors, assigns, and the officers, directors, agents,
11 servants, and employees of each of the foregoing, customers and/or licensees and those persons
12 acting in concert or participation with any of them, enjoining and restraining them from
13 continued infringement, including but not limited to using, making, importing, offering for sale
14 and/or selling products that infringe, and from inducing the infringement of the '208 patent prior
15 to its expiration, including any extensions;

16 C. An award of damages adequate to compensate for Defendants' infringement of
17 the '208 patent and enhanced damages and interest in accordance with 35 U.S.C. § 284 and
18 proof, including in lost profits, price erosion and/or reasonable royalty, and prejudgment and
19 post-judgment interest at the highest rates allowed by law;

20 D. Judgment declaring that this is an exceptional case under 35 U.S.C. § 285 and
21 awarding Plaintiff attorneys' fees and costs it has incurred; and

22 E. Such other and further relief, in law and in equity, as this Court may deem just
23 and appropriate.

24 **DEMAND FOR JURY TRIAL**

25 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Minerva demands a trial by
26 jury of this action.

1 Dated: April 11, 2017

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

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4 By: /s/ Vera M. Elson
Vera M. Elson

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6 Attorneys for Plaintiff Minerva Surgical, Inc.
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